#### IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA ex rel. ELLSWORTH ASSOCIATES, LLP,

Plaintiff-Relator,

Case No.: 2:19-cv-02553-JMY

v.

CVS HEALTH CORPORATION, et al.,

Defendants.

### MEMORANDUM OF LAW IN SUPPORT OF MOTION TO AMEND THE COURT'S ORDER UNSEALING THE SECOND AMENDED COMPLAINT

The Court ordered the unsealing of the Second Amended Complaint (SAC), without limitation, on May 6, 2022. Relator is out of compliance with that Order because Relator has not provided an unredacted copy of the SAC to Defendants. Defendants have asked Relator for an unredacted copy, without limitation, because (at a minimum) they need one to complete their investigation of Relator's allegations, and to comply with any notification obligations under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). To date, Relator has not provided an unredacted copy without limitation, and has taken the position that Relator's service of its own pleading is a discovery issue. That position is without merit and prejudicial to Defendants. The Court should resolve the dispute by amending its Order to state that Relator shall serve an unredacted copy of the SAC on Defendants within 24 hours.

#### 1. The SAC is a judicial record that is presumptively accessible to Defendants and must be disclosed to them without redaction

A qui tam complaint is a judicial record, not discovery material. Purcell v. Gilead Scis., Inc., 415 F. Supp. 3d 569, 574 (E.D. Pa. 2019). A judicial record "is a document filed with the court ... or otherwise somehow incorporated or integrated into a district court's adjudicatory proceedings." Id. Federal courts presume that the common-law public right of access attaches to

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judicial records, and use a balancing test to determine whether the party favoring secrecy has rebutted the presumption. As Judge Kearney explained in *Purcell*:

The presumption of access to judicial proceedings and records is not absolute and may be rebutted. The party seeking to overcome the presumption of access bears the burden of showing that the interest in secrecy outweighs the presumption. Here, Relators and the United States each must show that the material is the kind of information that courts will protect and that disclosure will work a clearly defined and serious injury to the party seeking closure. To overcome the strong presumption of access, we must articulate the compelling, countervailing interests to be protected, make specific findings on the record concerning the effects of disclosure, and provide an opportunity for interested third parties to be heard. We must conduct a document-by-document review of the challenged documents, provide specific examples of harm or articulated reasoning, and balance the competing interests between the public's right to access and a clearly defined and serious injury to the party seeking closure. When considering requests to keep documents sealed, courts generally lift the seal on the entire record except for specific documents that: (1) reveal confidential investigative methods or techniques; (2) jeopardize an ongoing investigation; or (3) harm non-parties.

*Id.* (internal citations omitted) Relator has not and cannot articulate "compelling, countervailing interests" sufficient to overcome the "strong presumption of access." None exist.

The Court ordered the unsealing of the SAC, without limitation. Defendants need an unredacted copy of the SAC to complete their investigation of Relator's allegations, and possibly to complete the briefing on their motion to dismiss. As explained below, Defendants also need an unredacted copy to fulfill any notice obligations they may have under HIPAA. Relator's noncompliance with the Court's Order is prejudicing Defendants by impeding their ability to ensure full HIPAA compliance and to prepare their defense.

The only plausible reason for redacting the SAC is to protect the privacy of the individual SilverScript enrollees identified in it. The redaction of information about those individuals on the

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<sup>&</sup>lt;sup>1</sup> For example, the information that Relator redacted from the SAC includes National Provider Identifiers (NPIs) for pharmacies, which may be used to locate or verify the locations of pharmacies, and may accordingly bear on Defendants' arguments concerning Relator's allegations about the application of state generic substitution laws to Defendants.

docket protects their privacy. The withholding of the same information from Defendants accomplishes nothing because the individuals are already SilverScript enrollees and Defendants need their identities to provide them with any notice under HIPAA. While Defendants agree that enrollee privacy should be protected on the public docket, Relator cannot rebut the presumption of access to prevent Defendants from accessing an unredacted version of the SAC.

# 2. Defendants need an unredacted copy of the SAC to comply with any notification obligations they may have under HIPAA

SilverScript is a HIPAA covered entity that must "notify each individual whose unsecured protected health information [(PHI)] has been, or is reasonably believed by [SilverScript] to have been, accessed, acquired, or disclosed as a result of [a] breach." 45 C.F.R. § 164.404(a)(1). SilverScript must also notify the U.S. Department of Health and Human Services (HHS) Office for Civil Rights (OCR) following the discovery of a breach of unsecured PHI to third parties. *See* 45 C.F.R. § 164.408(a). The HIPAA Privacy Rule states that a covered entity is not considered to have violated the HIPAA Privacy Rule when a workforce member of the covered entity takes PHI and gives it to her attorneys or to a health oversight agency for review. *See* 45 C.F.R. § 164.502(j). It is a potential improper disclosure if an alleged whistleblower discloses PHI to other persons not identified in §164.502(j). *See Id*.

Here, Ms. Miller (a limited partner in Relator) took PHI from SilverScript. It is undisputed that some or all of it was given to not only her attorneys and the U.S. Department of Justice but also to the Relator and a third-party transcription service called Rev.com. Based on information received from Relator, neither Ms. Miller nor her attorneys entered into a business associate agreement with Relator or Rev.com prior to the disclosure of PHI taken by Ms. Miller. It is unclear to Defendants whether 45 C.F.R. § 164.502(j) applies in connection with the otherwise impermissible disclosures of PHI to the Relator and Rev.com.

Defendants need the identities of the SilverScript enrollees alleged in the SAC to fulfill any obligation Defendants may have to give notice to those enrollees and OCR under the HIPAA Privacy Rule. Relator's noncompliance with the Court's Order is prejudicing Defendants by preventing them from giving such notice to affected individuals within 60 days, in alignment with the HIPAA Privacy Rule.

# 3. Defendants conferred with Relator and exhausted reasonable efforts at a negotiated resolution before filing this motion

Defendants began to raise concerns about the redactions to the exhibits attached to the SAC with Relator in June 2022. Defendants specifically requested an unredacted version of the SAC (including the exhibits) on August 2, 2022, and reiterated the request afterwards. Defendants sent a prior version of this motion to Relator on September 28, 2022 for discussion purposes. Defendants conferred with Relator by phone and email on September 29, 2022, and agreed to give Relator until 5:30 p.m. on October 4, 2022 to respond. The parties conferred by phone on October 4, 2022, and Relator offered to share an unredacted copy of the SAC in return for Defendants foregoing any use of newly-unredacted information in their reply in support of their motion to dismiss the SAC. Defendants declined. On October 5, 2022, Relator asked for additional time to respond. Defendants informed Relator that they would defer the filing of this Motion until Noon the next day. Realtor then declined to produce the unredacted SAC. This Motion followed.

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The Court should resolve the parties' dispute by amending its Order to state that Relator must serve an unredacted copy of the SAC on Defendants within 24 hours. The Court should also award attorney's fees and costs to Defendants because Relator could have obviated this motion by simply agreeing to Defendants' requests and complying with the Order of May 6, 2022.

Dated: October 6, 2022

## /s/ Lesli C. Esposito

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## **CERTIFICATE OF SERVICE**

I certify that on October 6, 2022, this document was filed electronically, that it is available for viewing and downloading from the ECF system, and that all counsel of record will be served by the ECF system.

/s/Lesli C. Esposito
Lesli C. Esposito